CDRH - Premarket Notification (PMN or 510(k)) for 1999
November 1999 Listings
WORLDWIDE MEDICAL TECHNOLOGIES SEEDING SPACERS

WORLDWIDE MEDICAL TECHNOLOGIES SEEDING SPACERS

Decision Date: November 5, 1999 **Received:** April 19, 1999

Applicant	WORLDWIDE MEDICAL TECHNOLOGIES, INC. 426 MAIN ST. NORTH P.O. BOX 505 WOODBURY CT 067980505
Contact	GARY A LAMOUREUX
510(k) Number	K991344 Summary in PDF
Regulation Number	892.5730
Decision	Substantially Equivalent (SE)
Statement/Summary	Statement Only
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Product Code	SOURCE, BRACHYTHERAPY, RADIONUCLIDE (KXK)
Type	TRADITIONAL
Third Party Review	No
Expedited Review	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1999

Mr. Gary A. Lamoureux
Worldwide Medical Technologies
426 Main Street, North
Woodbury, CT 06798

Dear Mr. Lamoureux:

Re: K991344
Worldwide Medical Technologies
Seeding Spacers
Dated: August 13, 1999
Received: August 16, 1999
Product Code: 90 KXK
Regulatory Class: II (two)
21.CFR 892.5730

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97).

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Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991344

Device Name: Worldwide Medical Technologies Seeding Spacers

Indications For Use:

The Worldwide Medical Technologies Seeding Spacers intended use is to provide space between radionuclide seeds during the introduction of radionuclide seeds into the body for Brachytherapy procedures. The anatomical site is typically the transperineal approach for radionuclide seed application in and around the prostate.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991344

EXHIBIT 1